

REMARKS

Reconsideration of the present application, as amended, is respectfully requested. The application, as amended, includes claims 1, 4-25 and 63-74, pending and under consideration. Without acquiescing in any of the rejections stated in the outstanding Action, in order to facilitate the allowance of the present application and issuance of a patent thereon, Applicant herein submits certain claim amendments for entry into the record. Applicant expressly reserves the right to further pursue any subject matter cancelled from the claims at a later time in this or a continuing patent application.

Applicant acknowledges and thanks the Examiner for the indication in the outstanding Office Action that claims 14 and 15 recite allowable subject matter. The Action states under the heading "Allowable Subject Matter" that these claims are "objected to as being dependent upon a rejected base claim, but would allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims." Applicant respectfully submits that the base claim (claim 9), as amended, is in condition for allowance, as discussed more fully below. Applicant therefore respectfully requests withdrawal of this objection.

The rejections stated in the outstanding Office Action are addressed in turn below.

REMARKS REGARDING REJECTION UNDER 35 U.S.C. §112

Claims 8, 50, and 57 are rejected in the outstanding Action under 35 U.S.C. §112 as including wording that lacks proper antecedent basis. Specifically, these three claims were rejected for including the phrase "said adding" without providing sufficient antecedent basis for the use of this phrase. This rejection is now moot as it relates to claims 50 and 57 because these claims are now cancelled. Claim 8 has been amended to remove the phrase considered to be objectionable by the

Examiner. Accordingly, Applicant respectfully submits that this rejection is overcome, and respectfully requests that this rejection be withdrawn.

REMARKS REGARDING REJECTION UNDER 35 USC §102(b)

Claims 1, 4-6, 44-48 are rejected in the outstanding Action under 35 USC §102(b) as being anticipated by Sodemann (“Sodemann”), U.S. Patent 6,166,007. This rejection is now moot as it relates to claims 44-48 as these claims are now cancelled. With respect to claims 1 and 4-6, however, Applicant respectfully traverses this rejection.

In traversal, Applicant submits that claim 1 and claims 4-6 (which depend from claim 1) cannot properly be found to be anticipated by the Sodemann ‘007 patent because each of these claims recites the following language: “wherein the lock solution comprises a citrate salt in a concentration range, in weight percent, of between about 10% and about 40%.” Applicant submits that the Sodemann ‘007 patent does not disclose any composition that has a concentration of a citrate salt within this range or even near to this range.

As noted by the Examiner, “Sodemann discloses the acid and/or salt will be used in a concentration effective to bring about the desired anticoagulation effort and such typical concentration of trisodium citrate in the range of 5 to 50 grams per liter.” (Office Action, Page 3; citing the Sodemann ‘007 patent col. 12 lines 24-43). It is important to realize, however, that the “weight percent” concentration unit recited in the subject claims is different than the “grams per liter” concentration unit stated in the ‘007 patent. Indeed, when the 5 to 50 grams per liter concentration range stated in the ‘007 patent is converted to a weight percent unit, this concentration range is equivalent to a range of about 0.5 to 5%, by weight, which does not overlap a concentration range of about 10% to about 40%, by weight, recited in pending claims 1 and 4-6. As such, Applicant submits

that the Sodemann '007 patent cannot be found to anticipate claims 1 and 4-6. Applicant therefore respectfully requests withdrawal of this rejection.

REMARKS REGARDING REJECTIONS UNDER 35 U.S.C. §103(a)

Claims 9-13, 17, 18, and 63 are rejected in the outstanding Action under 35 U.S.C. 103(a) as being obvious over Sodemann in view of Maginot et al. U.S. Patent 6,190,371. In reply, Applicant respectfully submits that the subject matter recited in claim 9, as amended, is allowable over the cited art. The outstanding Office Action indicates that the subject matter recited in claims 14 and 15 is allowable (if rewritten in independent form). Applicant submits that amended claim 9, which is herein amended to recite density and viscosity ranges similar to those recited in claims 14 and 15, is in condition for allowance for the same reasons. Although the density and viscosity ranges recited in claim 9, as amended, are broader than those in claims 14 and 15, Applicant submits that these broader ranges are also novel and nonobvious over the cited references. Furthermore, because claims 10-13, 17, 18 and 63 depend directly or indirectly from claim 9, Applicant submits that these claims are also in condition for allowance at least because the claims depend from an allowable claim, and for other reasons.

Claims 7, 16, 49, and 51-56 are rejected in the outstanding Action under 35 U.S.C. 103(a) as being unpatentable over Sodemann. This rejection is now moot as it relates to claims 49 and 51-56 as these claims are now cancelled. With respect to claims 7 and 16, however, Applicant respectfully traverses this rejection. Claim 7 depends from independent claim 1, which is believed to be in condition for allowance for the reasons stated above. Claim 16 depends from independent claim 9, which is believed to be in condition for allowance for the reasons stated above. Applicant therefore

submits that these claims are in condition for allowance at least because the claims depend from allowable claims, and for other reasons.

Claims 57-62 are rejected in the outstanding Action under 35 U.S.C. 103(a) as being unpatentable over Sodemann. This rejection is now moot as these claims are now cancelled.

Claims 19-25, and 64 are rejected in the outstanding Action under 35 U.S.C. 103(a) as being unpatentable over Sodemann. In support of this rejection, it is stated in the Action that:

Sodemann discloses an antimicrobial lock and a method of inhibiting or preventing infection and blood coagulation in or near a medical prosthetic device after the device has been inserted in a patient comprising elements and steps set forth in these claims. With regards percentage of bactericidal component weight based on the weight of the bactericidal component, of a citrate salt, it would have been obvious to one skilled in the art to apply such percentage according [sic] in order to accommodate a particular application. Applicant does not disclose any criticality for the claimed percentage.

(Office Action, page 6). Applicant respectfully disagrees with this assertion, and submits that there is no suggestion or motivation to be found in the cited reference, or in any other reference of record in this case, to make or use a lock solution having a bactericidal component in which more than 50 % of the bactericidal component, by weight, is citrate salt, as recited in the subject claims. Indeed, Applicant submits that a person of ordinary skill in the art, who would not have had prior knowledge of the bactericidal properties of citrate salt in a lock solution as described in the present specification, would find no motivation to prepare a catheter lock solution having a bactericidal component in which more than 50 % of the bactericidal component, by weight, is citrate salt.

With reference to the Sodemann '007 patent, Applicant submits that this reference does not disclose or suggest a catheter lock solution that includes a bactericidal component having the recited features. The compositions disclosed in the '007 patent include a taurinimide derivative for the sole purpose of providing bactericidal effect to the compositions, and the authors of the '007 patent

described catheter lock compositions including sodium citrate only for its known anticoagulation properties. Nevertheless, even if one were to consider the taurinimide derivative and the sodium citrate in the disclosed compositions to make up the “bactericidal component” of the catheter lock compositions described in the ‘007 patent, it is seen that the taurinimide derivative in each disclosed catheter lock composition is well over 50% by weight of the bactericidal component. In this regard, the ‘007 patent describes an “antimicrobial lock” at column 14, lines 10-14, that includes 13.3 grams/liter of taurolidine and 6.7 grams/liter tri-sodium citrate.

In view of the above, a person of ordinary skill in the art cannot have been motivated, prior to the present invention, to modify the compositions described in the ‘007 patent and provide a lock solution having a bactericidal component that is at least 50%, by weight, composed of a citrate salt, as suggested by the Examiner. The assertion that, “it would have been obvious to one skilled in the art to apply such percentage according [sic] in order to accommodate a particular application,” as stated in the outstanding Action, is bare, unsupported conjecture. The Examiner has not pointed to any suggestion or motivation in the prior art to make this modification, and Applicant therefore submits that this rejection is improper. Absent such a suggestion or motivation in the prior art, it is improper to reject these claims under Section 103(a). Applicant therefore respectfully requests withdrawal of this rejection.

Claims 5, 13, and 55 are rejected in the outstanding Action under 35 U.S.C. 103(a) as being unpatentable over Sodemann, and they are also rejected in the outstanding Action under 35 U.S.C. 103(a) as being unpatentable over Sodemann in view of Satoh et al. U.S. Patent 5,109,025. These rejections are now moot as they relate to claim 55 as this claim is now cancelled. With respect to claims 5 and 13, however, Applicant respectfully traverses these rejections. Claim 5 depends from independent claim 1, which is believed to be in condition for allowance for the reasons stated above.

Claim 13 depends from independent claim 9, which is believed to be in condition for allowance for the reasons stated above. Applicant therefore submits that these claims are in condition for allowance at least because the claims depend from allowable claims, and for other reasons.

NEW CLAIMS

Applicant would also draw the Examiner's attention to new claims 65-74. These claims are also believed to define patentable subject matter that is novel and non-obvious over the references of record. Applicant therefore respectfully requests an indication that these claims are in condition for allowance.

CLOSING

In view of the above, the Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 1, 4-25 and 63-74, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted:



Gregory B. Coy
Reg. No. 40,967
Woodard, Emhardt, Moriarty,
McNett & Henry LLP
Bank One Center/Tower
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456